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G3N NGA5 N294

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(54) System for delivery of drugs and therapeutic agents

(57) The container for the drug or agent, i.e. a syringe 4 or infusion bag, bears coded information 11 which is read by reader 2, and used to control automatic delivery device 1 for dispensing the drug or agent. The information may be coded as a barcode or a Smart card and may comprise the rate of delivery and other information such as the name of the drug. The patient may also carry a coded label which is checked against the code on the drug.

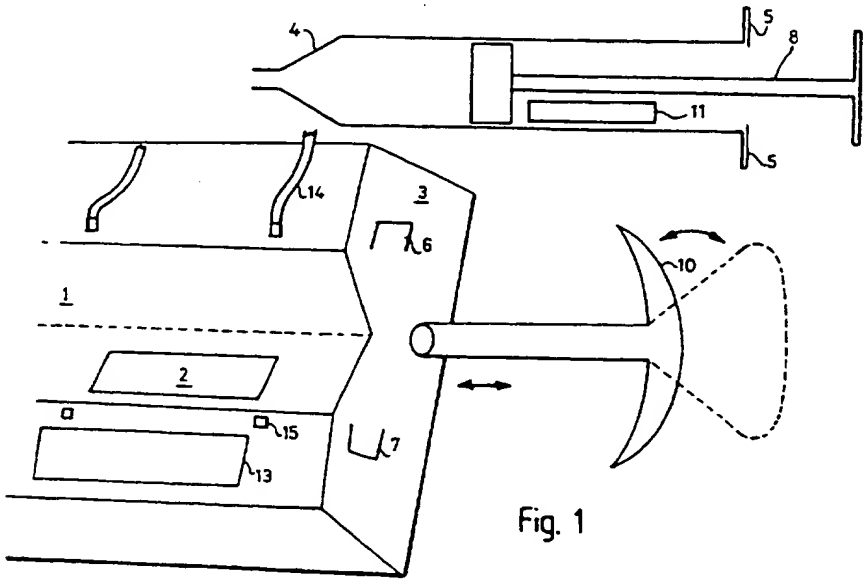

Fig. 1

GB 2 309 801 A

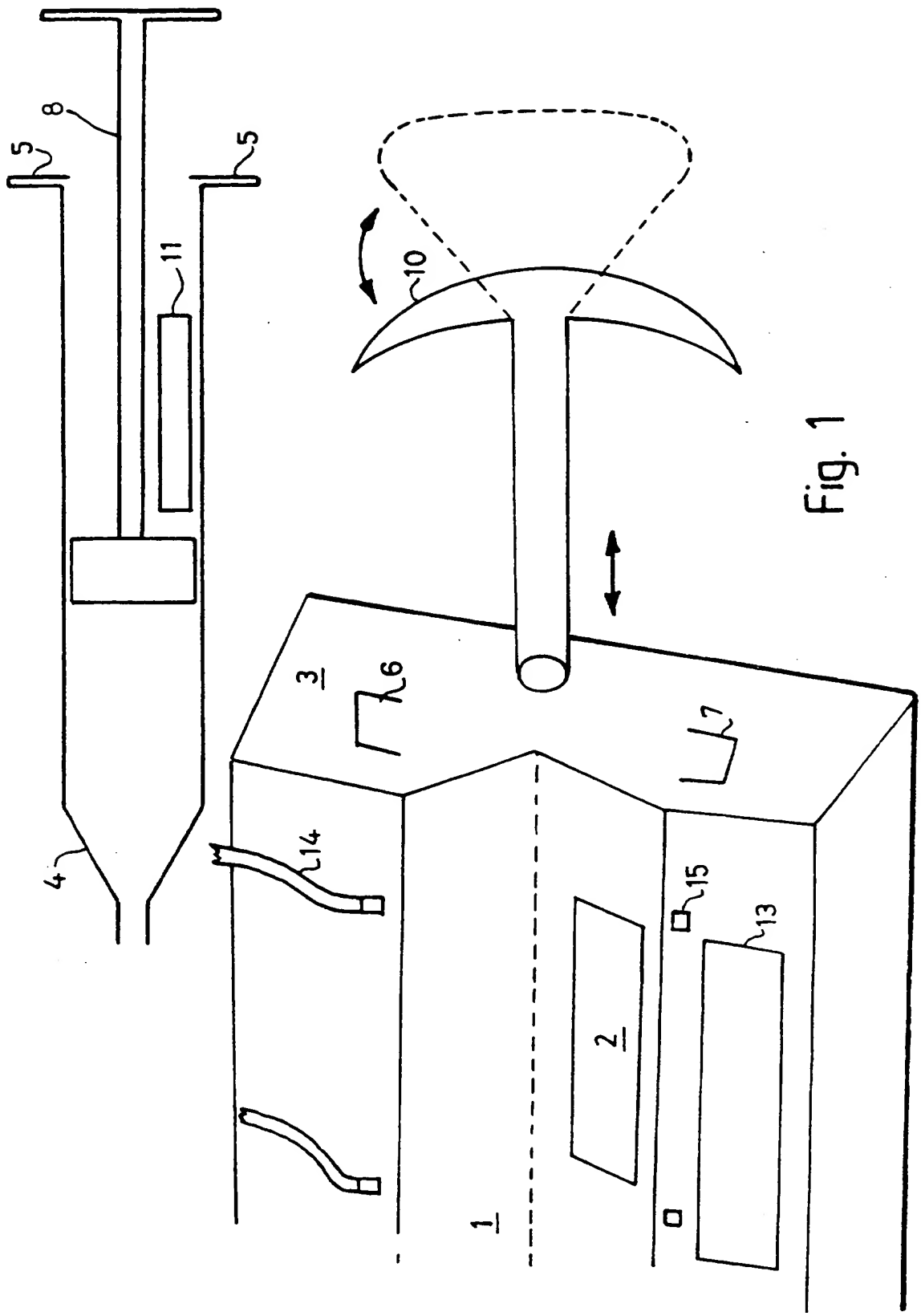

Fig. 1

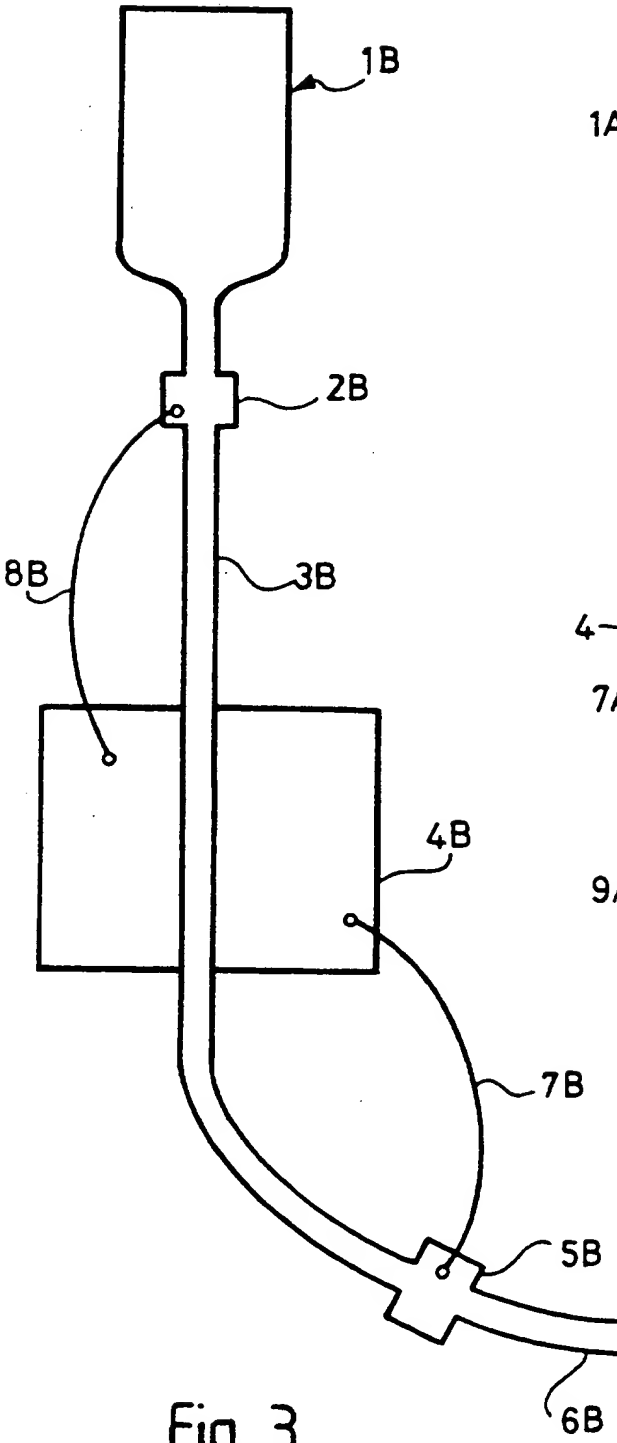

Fig. 3

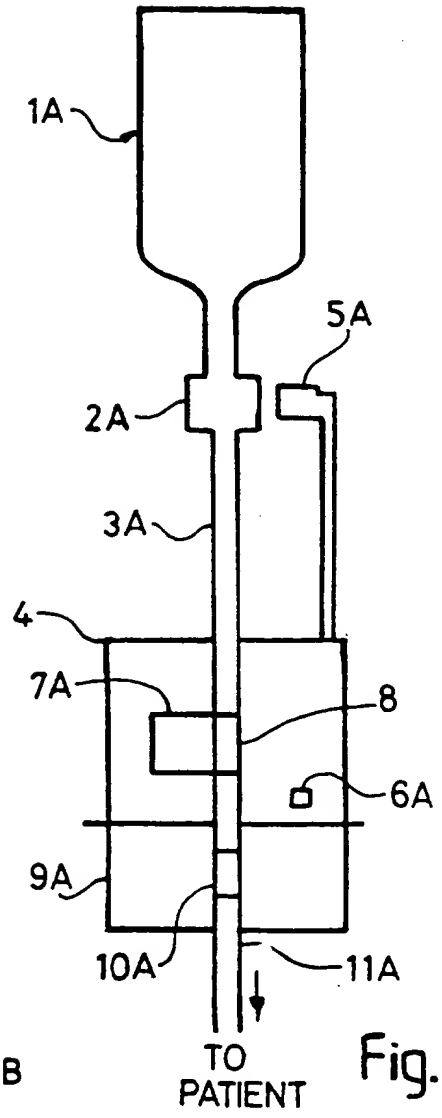

Fig. 2

A System for the Delivery of Drugs and Therapeutic Agents

This invention relates to a system for the delivery of medicinal drugs and other therapeutic agents, for convenience collectively referred to herein as therapeutic agents.

In medical practice therapeutic agents are given via syringe pumps for a variety of reasons. Examples are opiate and antiemetic drugs given in terminal care, chemotherapeutic agents in cancer therapy and antithrombolytic agents in myocardial infarct. Other uses for such pumps include asthma therapy, neonatology, anticoagulation and in fact any therapy whereby drugs have to be given in known and accurate quantities over precise time intervals. As practised at present syringe pumps require drugs to be drawn up to precise concentrations and loaded onto the syringe pump which then has to be set to the exact delivery rate. This is time consuming and is prone to human error.

Analogously, intravenous fluids, also included within the generic term "therapeutic agents", are given by means of a bag containing the fluid, a so-called giving set, and a drip counter. The bag has to be read by hand, its data recorded manually and the drip counter set at the desired rate. This process is also prone to human error.

According to the present invention there is provided a system for the delivery of therapeutic agents wherein coded information is affixed or incorporated onto the container of the therapeutic agent, reading means is provided for reading the coded information and control means responsive to the reading means is provided by which this information is utilised to control the administration of the therapeutic agent.

Such a means of controlling administration may be a syringe pump capable of reading the coded information and following the instructions inherent in the information to safely deliver the therapeutic agent at a prefixed rate. In an alternative form of system, a flow controller capable of controlling the rate of flow of a parenteral fluid from an infusion container is provided, which controller is capable of reading coded information held on the fluid container and controlling the rate of flow of the fluid at a prefixed rate.

One means for carrying the coded information is a barcode, to be read by a barcode reader incorporated in the syringe pump or flow controller.

In usual practice the system is envisaged as being used by drugs and infusion fluids that have been pre-packaged so that data relating to the drug or fluid used can be utilised by the delivery machine, be it a syringe pump or flow controller. The pre-packaging may be carried out by the manufacturer of the drug or fluid or by a pharmacist.

Thus, the coding system can be applied simply to an empty syringe. In this case any drug or fluid that this syringe holds will only be capable of being delivered through the complementary syringe pump at the rate specified by the coded information on that syringe, and the manufacturer or pharmacist is relied upon to fill the syringe with the correct fluid for that dosage. In a similar way it is provided that the coding system may be applied to the giving set, inclusive of tubing, of an infusion apparatus. Any bag of infusion fluid attached to this giving set or tubing would then only be capable of being delivered at the rate set by the coded information held on that giving set or tubing. These applications are termed "generic" coded delivery systems, as the syringes or giving sets used can be applied to any therapeutic agent. In the present invention, not only is it provided that encoded data be incorporated onto the tubing or bag, it is also provided for data to be held on a specific "infusion identifier" which will form the

interface between the bag and the flow controller. A possible disadvantage of generic systems is that no record is made as to the drug or fluid used or to its concentration.

The invention makes it possible for drugs to be delivered parenterally, either intravenously or subcutaneously for example, at pre-set delivery rates without the requirement for a trained nurse or doctor to be present to draw up and set the syringe pump. The administration would be made at the time of drug prescribing and dispensing, with the knowledge that the drug dispensed can only be delivered in a pre-set manner.

In an embodiment there is provided a syringe pump comprising a mechanically driven device that depresses the plunger of the syringe at a steady and uniform rate. This rate is set by the encoded data held on the drug's syringe and read by the syringe pump. Provision may nevertheless be made for the delivery rate to be altered as the clinical situation decrees by suitable able medical or nursing personnel.

In this embodiment, there is provided an access point for the syringe into which the syringe can be placed. Preferably this will be a suitably sized structure that complements the syringe's shape, most probably a cylindrical shape. In placing the syringe into this receiver the coded data will be read. The action of insertion may provide the movement necessary for reading to occur. A fixed single reader in the receiver will scan the coded data at this point of insertion.

The number of syringes a pump can control is not limited to one. A pump may have facilities to hold two syringes preferably, though not exclusively, controlling each one separately as determined by their individual encoded data.

Alternative methods of data transfer are also provided. Electromechanical means

such as specifically constructed syringes with designated toothed or holed structures that hold encoded data can be used. The pattern of the toothed structure, for instance on the wing of the syringe, can hold data specific to that syringe; similarly a series of holes in the body of the wing or plunger can be made to hold coded data.

In another embodiment, a flow controller is provided that can control the delivery of a fluid from an infusion bag, such as for example saline, dextran or blood. The infusion bag containing the fluid to be delivered is connected to the flow controller by tubing and the interface between these is termed an "infusion bag identifier". It is here that the coded details of the infusion bag are affixed, at the junction of flow controller and tubing, but not exclusively so; in other devices the flow controller may read the coded data directly from the infusion bag itself. The junction between infusion bag and tubing leading to the flow controller may alternatively be used as the best position for the "infusion specific identifier" to be placed, as it will allow repeated changes of the bag to occur. The flow controller reads the data on this infusion specific identifier by the action of movement required to affix it in position, or merely by an action of moving it past the reading device of the flow controller. The flow controller consists of apparatus that sets the delivery rate of the infusion fluid. Such a means is provided by the controlling of the aperture of a valve through which the fluid has to pass, the valve in this case can be a disposable component, or by controlling a drip counter device or standard programmable infusion rate device.

Preferred packaging envisaged for the therapeutic agent is an adapted syringe which will hold the drug in a stable manner. This may include a vacuum within the syringe and a seal that can be broken upon application to the syringe pump. Such a seal may exist at the nozzle or at the plunger end of the structure. The fluid in the syringe does not have to be held under vacuum. A system for breaking the seal of the syringe may characteristically involve a rubber or plastic

seal that can be pierced by an adapted needle for instance to provide patency and continuity with a system of tubing for delivery purposes. The drug is held in the syringe in a known concentration and at a fixed volume. It is envisaged that for any single drug there may be several different types of syringe, each holding a particular concentration and/or volume of the drug. The size of syringe is preferably kept constant, with only the concentration of the drug variable.

Also envisaged is a standard size of syringe through which all different types of drugs and concentrations will be stored and applied. The syringe structure will be compatible with holding drugs in solution and other syringe types will be capable of holding drugs stored as solids in powdered or other format ready to be dissolved prior to administration. This latter structure may involve the process of breaking the seal with a needle for the purpose of filling the syringe with solute from another syringe. Both syringes can be inserted into the syringe pump prior to use to enable them to be verified. Standard syringes containing drug and solutions to be mixed together prior to use, or two drugs together, may also be provided. A vacuum arrangement in one such syringe can then be used to fill the other prior to application into the pump.

The syringe storing the drug can be unpressurised and can be filled, in the case of drugs stored as a powder, by simple addition of solution. Similarly a powdered drug can be drawn up with solute into a syringe which has the desired delivery rate encoded onto it.

Generic syringes, that is syringes which are supplied empty and which are filled with whatever drug the medical practitioner specifies, can also be used. Generic syringes will have coded data that specifies their size and flow delivery rate but not coded data relating to the actual drug, by definition.

Combination of a flow controller and syringe pump into one device is possible to

enable the precise administration of certain drugs to infusion fluids.

The information encoded on the drug packaging, for example by means of a barcode, can include such parameters as the drug name, its READ code or other classification code, its manufacturer, its batch number and manufacturing date and expiry date as well as the volume of drug present and its concentration. Parameters relating to its delivery will include the rate of administration, which can be in millilitres per hour, and the length of time the drug is expected to be given over as well as a security code to ensure that there is no label damage or any label tampering.

It is envisaged that the system will be of great help to practitioners involved in the care of diabetic patients undergoing treatment with a sliding insulin scale. In such a clinical setting the syringe pump may be filled with a pre-coded syringe containing insulin at a particular concentration. The syringe may be coded so that it only delivers insulin at certain delivery rates upon the entering of clinical data from the patient in the form of blood glucose measurements or BM stix readings. The syringe may be programmable so that the doctor sets the time interval at which glucose readings have to be entered and the sliding scale details pertaining to the delivery of insulin, if so desired. The syringe will not operate outside of these ranges and may offer warnings when data is required. A twin syringe pump may be used, supplying both glucose and insulin infusions as an improved control method.

Additionally it is envisaged that such a coded delivery system be used to treat hyperkalaemic patients receiving insulin and glucose therapy, with a programmable element incorporated to set delivery rates in response to blood potassium levels. It is noted that generic syringes may also be utilised. A series of coded sliding scale delivery rates may be encoded onto the syringe, either generic or pre-filled, from which a doctor may choose. Alternatively syringes may come in a variety

of types, each with a particular pre-set sliding scale encoded onto it.

In the case of infusions of intravenous fluids, further data may be encoded. Blood transfusions will benefit from enhanced protection to prevent adverse reactions by using coded delivery systems. The tubing used in the giving set may be coded as follows:- the infusion bag containing blood is coded, with additional data relating to blood type and blood type idiosyncrasies; the tubing attached to the patient's vein is also coded, but with the patient's blood type and blood type idiosyncrasies, in addition to his name and identification number or NHS number. Both of these, the blood bag and the tubing affixed to the patient, are attached to the flow controller which reads their respective encoded data and ensures a correct match has occurred. Rather than human vigilance check for each and every bag of blood that is given, this system enables just the initial siting of the iv access tubing to be correctly matched with the patient; thereafter any blood given to the patient must be compatible with the tubing affixed to the patient.

It is not necessary for the actual tubing affixed to the patient to be coded. It is also envisaged that a "specific patient identifier" can be used that interfaces between the flow controller and the tubing leading to the patient's vein.

A "double coded delivery system" can be additionally used for any therapy in which it is critical for therapy where multiple bags are given to be accurately matched to the patient. Chemotherapy is such a critical therapy. In this case the "specific patient identifier" can be encoded by the hospital pharmacist, for instance, with details of the therapy that the patient is going to receive. Only this therapy can then be given to the patient, as any other therapy will be blocked by the flow controller, which will match the therapy in the infusion bag with data held on the "specific patient identifier". The flow controller will read data on the infusion bag by means of, but not exclusively, an "infusion bag identifier" that will interface between the infusion bag and the flow controller.

Provision may also be made for encoded data to be applied not only at the time of manufacture of syringe, tubing or infusion bag,but also, in special circumstances, for coded data to be affixed to syringes, tubing or infusion bag (via their respective specific patient identifiers if necessary) by a worker in the hospital setting, for the purposes of correct patient identification, but not exclusively.

Yet again, provision may be made for the syringe pump or flow controller to respond to data held on Smart cards or similar data-holding equipment belonging to medical practitioners and nursing staff. Additionally the further data required may take the form of coded data that is personal and/or pertaining solely to the patient. This may be coded data held on the patient's wrist band, or held on a Smart card owned by the patient or held in coded format on the patient's notes. Such a provision enables a syringe or flow controller only to operate upon recognition of data recognised from such a Smart card, in such a manner as to record who initiates or changes therapy, and to allow only recognised personnel to operate the machines. Such a system helps to prevent unauthorised access to delivery devices and acts as a record of administration.

Password protection may be incorporated to enable only recognised users to operate the pump. Such passwords may be set by medical staff or by the patient, as is appropriate to the clinical situation. A log is kept of the activity of the pump or flow controller, principally noting the drug administered, the time treatment commenced, ended, and the dose of drug given. Further data such as cumulative drug dosage, average comsumption etc., may be given. Where two drugs are administered, say in a twin syringe pump, then the above data will be available for each individual drug administered.

Additionally certain drug containers may hold coded data relating to contra-indications that prevent them from being given with other drugs. For instance, if two separate drug syringes are inserted into the twin syringe holders in a twin

syringe pump and one of them contains a drug that was contraindicated to the drug held in the other syringe then the pump would make this apparent and not operate.

The invention also makes it possible to deliver pre-set fluid delivery rates whilst utilising standard infusion sets in the case of parenteral fluid delivery. Fluids that are envisaged as suitable would include dextrose solutions, saline solutions, plasma expanders and blood products.

It is possible to code any intravenous infusion bag with the coded information and thus enable it to be safely delivered at prefixed rates at time of manufacture. Medical staff are able to choose an infusion bag with a specific delivery rate, say for example 50 ml per hour or 150 ml per hour. Intravenous infusion bags may, in addition to the coded data, also include a simple visual colour coded display which would indicate their pre-set fluid delivery rates. The invention prevents free flow by not allowing the automatically controlled drip counter to run at anything other than its rate set by the coded data held on the infusion bag.

The data relating to fluid flow may be stored on a datalogger at the flow controller and be available for analysis at any time. A display may be provided, capable of showing cumulative dosages with time, average dose delivery rates, peak dose delivery rates as well as time periods relating to cessation of flow and so on. It will be possible to add data to this log of dosage delivery such as time of adding additive medicines to the fluid bag, doses of such medicines, and consequentially their delivery rates, cumulative dosage delivery, concentration and so forth.

Although envisaged to perform with infusion bags working under the effects of gravity the system does not exclusively have to. Infusion systems whereby pressurised compartments propel the fluid from the infusion bags may also be used. Such systems are often delivering fluid with a 15% error in delivery rates, and the usage of coded information to control a flow counter will minimise this

error.

Incorporated into a syringe pump may be a display means that enables the encoded data to be witnessed. Usually this will be by means of an LCD display but alternatively display could occur by means of transferring data to a PC and thereby utilising the display monitor attached. Additionally it will be possible to display the encoded data in an auditory fashion by transferring data to a PC with sound capabilities. Display means may also include the capability to warn the patient or medical practitioner that there is a problem and more usually to indicate that there are no problems. The display may incorporate an LCD display which has a fixed 5 second display and via which sequential data relating to the drug can be given.

With regard to fluid administration, the invention may provide for warnings that the time for completion is approaching. Again the data pertaining to cumulative dosage and time of delivery will be available. It is envisaged that the invention will be most useful clinically with regard to iv fluid administration where critical importance is placed upon rate of administration. Blood transfusions, antithrombolytic administration, and administering of fluids when an additive drug has been added to the bag (such as added potassium) are such critical situations. In paediatric neonatology such careful fluid administration is important because of the small volumes being delivered.

A datalogger may be used to hold data on delivery rates from either a syringe pump or flow counter and can later be downloaded to a PC for analysis. A serial port connection on the syringe pump or flow counter may be connected to a modem for means of a doctor or nurse interrogating the drugs delivery. In this same way provision is made for the flow rate to be altered, if required, by a doctor or nurse.

Provision may also be made for data to be made available, to either the syringe pump or flow controller, relating to patient details and clinical parameters such as pulse rate, blood pressure, temperature, respiratory rate, biochemical assays, pathology assays for instance, but not exclusively. In this case, provision is made for the pump to be programmable so that certain drugs can be delivered not only in accordance with data coded on the drug itself but also in response to clinically important and relevant data. Hence the delivery of an opiate that is pre-set according to encoded data on the opiate syringe can also be dependent upon data fed to the pump regarding the patient's respiratory rate or level of pain experienced (patient controlled delivery), within certain programmable limits. The delivery of blood can be made to be influenced by data relating to temperature or to blood pressure and pulse, or the delivery of an intravenous plasma expander can be made to be influenced by central venous pressure readings, in addition to the pre-set rates inherent in its own design.

The accompanying drawings diagrammatically show embodiments of the invention. In the drawings:-

Figure 1 shows a coded syringe delivery system;

Figure 2 shows a coded infusion delivery system; and

Figure 3 shows a double coded infusion delivery system.

An example of a coded syringe pump delivery system is given in Figure 1. A syringe port 1 with decoder 2 is shown in part in a syringe pump 3. A syringe 4 is inserted to lie in the syringe port 1 with its wings 5 secured at recesses 6 and 7. The syringe's plunger 8 lies on top of the depressor shaft 9 and makes contact with the depressor 10 (which is shown attached to the depressor shaft). The depressor is a movable element which can lie flat to allow the syringe to be

inserted and which turns upwards over 90 degrees to enable it to depress the syringe's plunger. The syringe pump's decoder 2 reads the syringe's coded information 11 and thus primes the pump with the data it requires to function. A mechanical device (not shown) moves the depressor shaft 9 inwards to the machine at a rate predetermined by the data held in the syringe's coded data 11. An LCD display 13 shows the coded data in a visual form, including the name of the drug and its delivery rate. A cord 14 secures the syringe in place by looping around the corresponding hook 15.

An example of a coded infusion system is given in Figure 2. An infusion bag 1A with infusion specific identifier 2A is connected to tubing 3A that connects with a flow controller 4A. Flow controller 4A reads the coded data held on the infusion specific identifier 2A by means of a reader 5A and translates this data via an embedded processor 6A to control the flow rate via a mechanical mechanism 7A which controls the variably sized valve or restriction 8A. A drip counter device 9A may be present and a drip reader 10A to verify flow rate. Fluid is delivered along tubing 11A to the patient.

An example of a double coded infusion delivery system to be used in blood transfusions is shown in Figure 3. A blood bag 1B with blood identifier coded data 2B is connected to tubing 3B and connected to a flow controller 4B. A patient specific identifier 5B is fixed to tubing 6B that connects the patient to the flow controller. The flow controller 4B reads the blood identifier coded data 2B as well as the patient specific identifier 5B and operates under instructions if the two data sets are compatible. This reading is made by means of cable 7B linking the patient specific identifier 5B to the flow controller and by a cable 8B linking the blood identifier coded data 2B to the flow controller.

The infusion pump controller is enabled to read the barcode or other such code on the fluid bag by means of a hand-held barcode reader. This reader is attached to

the controller and is moved to the bag for reading. In the case where the patient's data need also be read, such as in the administration of blood products, the hand-held barcode reader can be made to read the barcode (or other code) enscribed onto the patient's wristband (or smartcard etc.) as well. Both sets of data will be processed by the controller and either enable the infusion to proceed or not proceed, as determined by the compatibility of the data read.

Claims

1. A system for the delivery of therapeutic agents wherein coded information is affixed or incorporated onto the container of the therapeutic agent, reading means is provided for reading the coded information and control means responsive to the reading means is provided by which this information is utilised to control the administration of the therapeutic agent.

2. A system according to claim 1, wherein the coded information is incorporated in a barcode.

3. A system according to claim 1, wherein the coded information is incorporated in a Smart card.

4. A system according to any of claims 1 to 3, wherein the coded information includes its prescribed rate of delivery.

5. A system according to claim 4, wherein the coded information also includes at least one of the name of the therapeutic agent, its classification code, its manufacturer, its batch number, its manufacturing and/or expiry of use date, its volume, its concentration.

6. A system according to any of claims 1 to 5, wherein the coded information is applied to a syringe and a syringe pump reads the coded information and follows the coded information to deliver the therapeutic agent only at the rate specified in the coded information.

7. A system according to any of claims 1 to 5, wherein the coded information is applied to an infusion bag and the coded information is read and interpreted by

a flow controller for the parenteral fluid to deliver the fluid only at the rate specified in the coded information.

8. A system according to claim 6 or claim 7, wherein the syringe pump or flow controller self adjusts its delivery rate to match the coded information.

9. A system according to claim 7, wherein a patient also carries a card bearing the coded information and the flow controller is adapted to deliver the parenteral fluid only if the coded information carried by the patient matches that on the infusion bag.

10. A system according to claim 9, wherein the coded information is also carried by an infusion identifier which forms the interface between the infusion bag and the flow controller.

11. A system according to claim 6, wherein the syringe pump has an access point adapted to receive the syringe bearing the coded information and this information is read by the action of locating the syringe at the access point.

12. A system according to claim 11, wherein the coded information is scanned by a reader as the syringe is located in place.

13. A system according to claim 11 or claim 12, wherein the syringe is a sealed syringe and the seal is broken when the syringe is located in place in the syringe pump.

14. A system according to any of claims 1 to 13, wherein a syringe pump and a flow controller are combined into a single device to enable the administration of a drug to a parenteral fluid.

15. A system according to any of claims 1 to 14, wherein the coded information includes a security segment to ensure that a syringe or infusion bag having a damaged label or a tampered-with label is not used.

16. A system according to any of claims 1 to 15, wherein the coded information includes a password to enable the syringe or infusion bag to be used only by one or more specified persons.

17. A system according to any of claims 1 to 16, having a display means associated with the syringe or flow controller.

18. A system according to any of claims 1 to 17, having a data logger associated with the syringe pump or flow controller.

19. A system substantially as hereinbefore described with reference to Figure 1 or Figure 2 or Figure 3 of the accompanying drawings.

The Patent Office

17

Application No: GB 9701904.6 **Examiner:** David Mobbs
Claims searched: 1-19 **Date of search:** 21 March 1997

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.O): G3N NGA5, NG1A4, NG1A9.

Int Cl (Ed.6): A61M 5/00, 5/14, 5/142, 5/168, 5/172.

Other: ONLINE: WPI.

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X, Y	EP 0,588,427 A	(BELLIFEMINE) - see figure 15 and columns 7-8.	X: 1, 2, 4, 7, 8 at least; Y: 9 at least.
X	EP 0,364,010 A	(C.R. BARD INC.)	1, 3 at least.
X, Y	WO 95/28190 A	(SIMS DELTEC, INC.) - see page 5 paragraph 2.	X: 1,2 at least; Y: 9 at least.
X, Y	WO 94/12235 A	(ABBOTT LABORATORIES) - see page 2 paragraph 3, page 3 paragraph 1, and page 5 paragraphs 1 and 2.	X: 1, 2 at least; Y: 9 at least.
X, Y	WO 94/08647 A	(THE GENERAL HOSPITAL CORPORATION) - see page 16 paragraph 2.	X: 1, 3, 5, 6 at least; Y: 9 at least.

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

The Patent Office

18

Application No: GB 9701904.6 **Examiner:** David Mobbs
Claims searched: 1-19 **Date of search:** 21 March 1997

Category	Identity of document and relevant passage		Relevant to claims
X, Y	WO 93/12828 A	(ABBOTT LABORATORIES) - see figure 3.	X: 1,2 at least: Y: 9 at least.
X, Y	US 5,317,506	(ABBOTT LABORATORIES)	X: 1-5, 7-8 at least; Y: 9 at least.
X, Y	US 5,153,827	(OMNI-FLOW, INC.)	X: 1-5, 7-8 at least; Y: 9 at least.
X, Y	US 5,078,683	(BLOCK MEDICAL, INC.)	X: 1, 2, 4, 5, 7 at least; Y: 9 at least.
X, Y	US 4,978,335	(MEDEX, INC.)	X: 1, 2, 4-6 at least; Y: 9 at least.
Y	US 4,857,716	(CLINICOM INCORPORATED) - see column 18 and figures 2 and 3.	9 at least.

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Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.